

## **NONTECHNICAL ABSTRACT OF PROTOCOL**

Many patients have advanced cancer that has not responded to standard therapies. For these patients, a new approach to treat their cancer (tumor) will be tested. Animal studies have been done using cancer cells into which a cancer fighting gene has been placed. When these modified cancer cells are returned to the animal the animal can fight the cancer cells better. The returning of the gene modified cancer cells can be helpful in fighting the cancer cells in several ways.

1. Injecting tumor cells under the skin has shown to increase the responses of the animal's white cells in fighting the tumor cells.
2. Before returning the cancer cells, they can be mixed with the patients own normal cells made to release a potent white cell activating factor (interleukin 4) by placing the gene for interleukin-4 into the normal cells mixed with the tumor cells. If these gene modified cells are used, the release of interleukin-4 by the normal cells mixed with the cancer cells further increases the ability of the animal's white cells to fight the cancer cells by activating these white cells.

This protocol is designed to mimic the results obtained with the animals.

Patients with cancer who have not responded to therapy will have a piece of their cancer cut out as well as a piece of skin and brought to the laboratory. In the laboratory the skin cells will be grown. The interleukin-4 gene will be put into the patient's normal cells (fibroblasts) grown from the skin. The patient's cancer cells are then mixed with the cells producing interleukin-4. These cancer cells and fibroblasts are then injected under the skin of the patient. In a few weeks white cells are removed from the area of injected cancer cells and grown to large numbers in the laboratory in the presence of interleukin-2 and interleukin-4 for special studies. During this time and afterwards the patient is watched for signs that the therapy may be helping destroy their cancer. Since this therapy is new, it is not known how well it will work in people. The patients will also be watched for possible harmful effects from the therapy. After many patients with many different kinds of cancer have this new therapy, the doctors will be able to tell how safe this new therapy is and begin to assess how well it works.